

SKYTEC TX4524

The manufacturer: Globus [Shetland] Ltd.
T2 Trafford Park, Twining Road,
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.

Confirms conformity to: PPE Regulation (EU) 2016/425
And the standard(s): ENISO21420:2020, EN374-1:2016+A1:2018 & EN374-5:2016

Of the following PPE product(s):
SKYTEC TX4524 – Biodegradable nitrile powder Free disposable 4.5mil Glove

The Notified Body SATRA Technology, [NB No. 2777]
performed the EU Type-Examination, [Module B], and issued the EU Type-Examination Certificate:
2777/20616-01/E02-01

The PPE is subject to the conformity assessment procedure, conformity to type based on internal production control plus supervised product checks at random intervals, [Module D], under the surveillance of the Notified Body:
SGS Fimko Oy, [NB No. 0598]

Also

Medical Devices Directive 93/42/EEC as amended, Medical Devices Regulation (EU) 2017/745 as amended (effective from 26/05/2021), and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

Signed for and on behalf of:
Globus [Shetland] Ltd/, T2 Trafford Point, Twining Road,
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.



Name: Mr. Christian Halford
Function: Regulatory & Quality Director

Date of issue: 14-July-22

EU Representative:
Globus EMEA Ltd
51 Dawson St
Dublin
D02 AN25 Ireland

SKYTEC TX4524

The manufacturer: Globus [Shetland] Ltd.
T2 Trafford Park, Twining Road,
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.

Confirms conformity to: UK Regulation 2016/425 On PPE
And the standard(s): ENISO21420:2020, EN374-1:2016+A1:2018 & EN374-5:2016

Of the following PPE product(s):
SKYTEC TX4524 – Biodegradable nitrile powder Free disposable 4.5mil Glove

The Approved Body SATRA Technology, [AB No. 0321]
performed the EU Type-Examination, [Module B], and issued the EU Type-Examination Certificate:
AB0321/20855-01/E02-01

The PPE is subject to the conformity assessment procedure, conformity to type based on internal production control plus supervised product checks at random intervals, [Module D], under the surveillance of the Approved Body:
SGS UK Ltd, [AB No. 0120]

Also

Medical Devices Directive 93/42/EEC as amended, Medical Devices Regulation (EU) 2017/745 as amended (effective from 26/05/2021), and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

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Name: Mr. Christian Halford
Function: Regulatory & Quality Director

Date of issue: 14-July-22

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